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Scanning electron microscopy evaluation of aligner fit on teeth

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ABSTRACT

Objectives: The fitting of aligners on anchorage teeth is a crucial factor in clear aligner orthodontics. The purpose of this experimental study was to evaluate the fitting of two aligner systems, Invisalign and CA-Clear Aligner, using scanning electron microscopy (SEM).

Materials and Methods: Passive aligners (Invisalign and CA-Clear Aligner) were adapted on resin casts obtained by stereolithography (STL) files of a patient, and then sectioned buccolingually. Upper and lower central incisors, upper and lower first premolars, and upper and lower first molars were the regions analyzed. Representative microphotographs of sections were taken with a scanning electron microscope (SEM); a total of 160 micrometric measurements were obtained and analyzed with ANOVA tests.

Results: Invisalign provided an overall better fit on lower incisors ($F = 11.48$, $P = .0095$) and on lower molars ($F = 19.93$, $P = .0012$). Considering the different regions, Invisalign provided better fit at the gingival edge of the buccal aspect on lower incisors ($F = 11.33$, $P = 0.0056$) and at the gingival edge of the lingual aspect on upper premolars ($F = 5.34$, $P = 0.0047$). On the upper molars, Invisalign provided better fit at the gingival edge of the buccal aspect, while CA-Clear Aligner provided better fit at the buccal maximum convexity, on the buccal cusp, on the occlusal groove and at the palatal cusp. On lower molars, Invisalign showed a more accurate fit at the buccal aspect points.

Conclusions: Invisalign and CA-Clear Aligner exhibited comparable fit on anchorage teeth. Invisalign provided better fit at the gingival edges of aligners, while the CA-Clear Aligner provided better fit on complex occlusal surfaces. (*Angle Orthod.* 0000;00:000–000.)

KEY WORDS: Aligners; Fitting; SEM; Microscopy; Invisalign; CA-Clear Aligner

INTRODUCTION

Thermoplastic appliances have a long history in orthodontics. However, only in recent years and thanks to the innovations based on applied biomechanics and biomaterials design and engineering, clear aligner therapy (CAT) has become a possible orthodontic option for several clinical conditions.¹

The existing literature demonstrated that CAT is effective in aligning and straightening the arches with better results for mild to moderate crowding (from 1 to 6 mm) when compared with results obtained with fixed appliances.² The ability of aligners to extrude, derotate, and apply root torque on teeth has been questioned.² As a result of these tooth-movement concerns, many clear aligner treatments have been completed without extractions. This may put an increased emphasis on mandibular incisor proclination to relieve crowding during CAT. Hennessy et al. performed a randomized clinical trial in which patients were treated with buccal fixed appliances (MBT prescription) and Invisalign (Align Technology, San Jose, Calif), demonstrating

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that CAT proclined mandibular incisors to a degree similar to fixed appliances and could be used to treat mild mandibular arch crowding in a comparable way.³

Improvements in aligner materials, ability to apply force systems and staging of tooth movement have enabled the treatment of more complex malocclusions with more precise and predictable outcomes.^{4,5} Grünheid et al.⁶ demonstrated that, in nonextraction cases, Invisalign aligners are able to achieve predicted movement with high accuracy. Khosravi et al.,⁷ in a retrospective study on 120 patients, showed that the Invisalign appliance was relatively successful in managing overbite. Changes in incisor position were responsible for most of the improvements in the deep-bite and open-bite groups.

Incisor torque, premolar derotation and molar distalization can be performed using aligners with forces and moments that are consistent with those previously reported.⁸ Especially for anterior teeth, the literature CAT outcomes with contrasting results regarding predictability.^{2,7,9} Unpredictability could be the result of the loss of anchorage.

Anchorage units are necessary to counteract undesired movements and to increase the predictability of programmed movements. Thus, the fit of the aligner on the anchorage teeth is a crucial factor for success in clear aligner orthodontics.

However, despite the widespread use of the technique, data related to the “play” between aligners and teeth are not available. Therefore, this study was designed to determine how well aligners fit the teeth and whether there were differences in fit between aligners made by Invisalign (Align Technology) and CA-Clear Aligner (Scheu-Dental, Iserlohn, Germany).

MATERIALS AND METHODS

Stereo lithography interface format (STL) files obtained by intraoral scanning (iTero Element (Align Technology)) of a patient with a Class I malocclusion and need for minor tooth movement, along with clinical records (digital intraoral and extraoral pictures, orthopantomography, and lateral x-ray) were sent to Align Technology and Scheu-Dental. Intraoral scanning was selected because it provides accurate digital information.^{10,11} Virtual setups were obtained based on the same clinical prescription provided by an expert operator in CAT. Therefore, the virtual set-up was the same for both systems.

Resin casts (methacrylic acid esters, proprietary pigment; Form 3D printer [Formlabs, Somerville, MA]) were obtained from the STL files (Uniontech Lab, Paderno Dugnano, Italy). These were then used to collect the measurements and perform the analysis.

Cast surfaces were properly cleaned and the first aligners, prescribed without active forces on the teeth, were adapted on the resin casts. Each cast was mounted on an aluminum stub and sectioned buccolingually with a cutting machine (Well Diamond Wire Saw Inc, Norcross, Ga) under continuous water irrigation, to prevent frictional heat which might result in smearing the sample.

Samples were then oriented to section perpendicular to the long axis of the investigated teeth. Upper central incisors, lower central incisors, upper and lower first premolars, and upper and lower first molars were the regions analyzed.

Once the sample was obtained by sectioning, coating was performed for scanning electron microscope (SEM) imaging. Each cross section was covered with a 10-nm layer of gold particles (99% Au) with a specific high-pressure machine (Cressington High Resolution Sputter Coater 208HR, Cressington Scientific Instruments, Watford, UK). Sputter coating prevents charging of the specimen, which would otherwise occur due to accumulation of static electric fields. It also increases the number of secondary electrons that can be detected from the surface of the specimen in the SEM and, therefore, increases the signal-to-noise ratio.

Each sample was then analyzed with a high-performance SEM (SEM JSM-6490LA, JEOL Inc, Peabody, Mass)^{12,13} having a beam voltage of 15kV and working distance of 10 mm, an embedded-energy dispersive x-ray analyzer, and a resolution of 3.0 nm, providing images of a sample by scanning it with a focused beam of electrons. The electrons interact with atoms in the sample, producing signals that contain information about the sample's surface topography and composition. The electron beam is scanned in a raster scan pattern, and the beam's position is combined with the detected signal to produce images. By scanning the sample and collecting the secondary electrons that are emitted using a special detector, an image displaying the topography of the surface is created.

Representative microphotographs at 65× or 140× magnification were obtained, then analyzed at the Department of Nanomaterials, Center for Synaptic Neuroscience, Italian Institute of Technology, Genoa, Italy (Figure 1). A total of 160 points on tooth surfaces were included for the measurements (Figure 2). For each point, ten micrometric measurements were taken using ImageJ (NIH ImageJ Software, <https://imagej.nih.gov/ij/>), an open source image processing program designed for scientific multidimensional images.¹⁴

Statistical Analysis

Data were expressed as mean \pm standard deviation (SD). Normality was evaluated with the Shapiro-Wilk

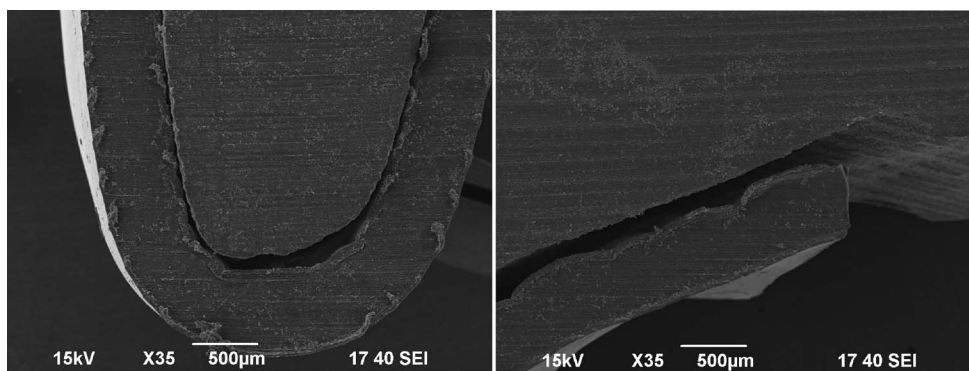


Figure 1. SEM image: interaction between aligner and tooth; gingival edge of the aligner.

test and homogeneity with the Levene and Brown-Forsythe tests. Repeated-measures ANOVA was performed. The Akaike information criterion and the Bayesian information criterion to estimate autocorrelation structure were used. An additional error term (subjects/treatment) corresponding to the variance for subjects was included in the statistical model. In this way, the variance for subjects was physically separated in the output. The effect of treatment was considered significant at $P < .05$. Tukey post hoc analysis was used to adjust for multiple comparisons. Two-way ANOVA was performed to analyze intra- and intergroup differences for every point. Bonferroni correction was used when required. Statistical analysis was performed using the R statistical package (version 3.0.1, R Core Team, Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Invisalign and CA-Clear Aligner appliances displayed comparable performance in terms of fit on teeth (Table 1). Two-way repeated measure ANOVA was used to test the differences in means between Invisalign and Clear Aligners. Stratification for point of measurement was also performed. Invisalign exhibited an overall better fit according to the measurements for lower incisors ($F = 11.48$, $P = .0095$) and for lower molars ($F = 19.93$, $P = .0012$). When considering every measurement point, there were no significant differences between the two systems for aligner fit on the upper incisors (Figure 3).

Invisalign exhibited a better fit at the gingival edge of the buccal aspect on lower incisors ($F = 11.33$, $P = .0056$). For the other points analyzed on lower incisors, no statistically significant differences were detected (Figure 4).

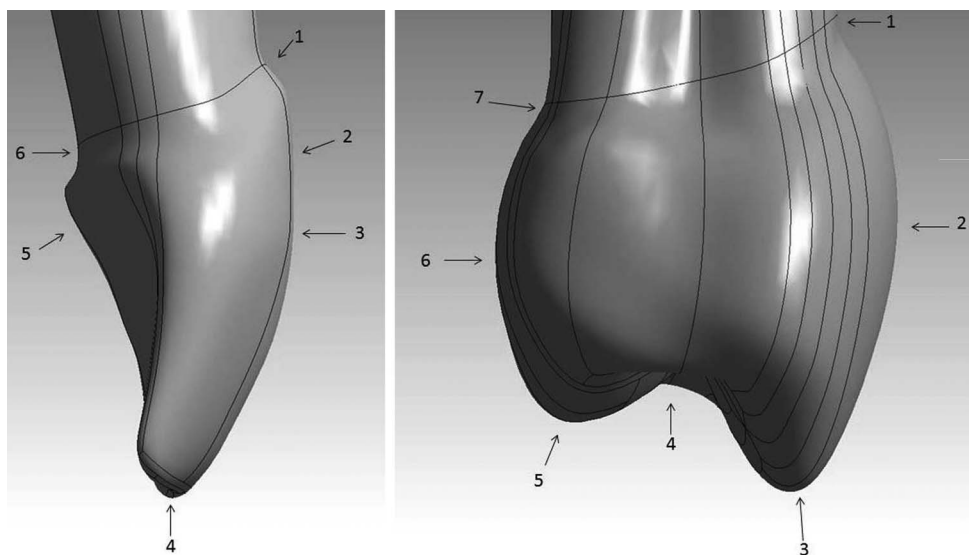


Figure 2. For anterior teeth, measurements were taken at six points: 1. Buccal gingival edge, 2. Half distance between border and maximum convexity, 3. Maximum convexity, 4. Incisal edge, 5. Cingulum, 6. Lingual gingival edge. For posterior teeth, measurements were taken at seven points: 1. Buccal gingival edge, 2. Maximum convexity of buccal surface, 3. Buccal cusp, 4. Central groove, 5. Palatal cusp, 6. Maximum convexity of lingual surface, 7. Lingual gingival edge.

Table 1. Comparison of Fit Between Invisalign and CA-Clear Aligner

Region	Invisalign		CA-Clear Aligner	
	Mean (μ m)	SD	Mean (μ m)	SD
Upper incisors	112.64	27.63	151.09	84.38
Lower incisors	102.74	29.30	173.97	81.24
Upper premolars	158.64	71.43	161.53	89.29
Lower premolars	145.29	96.79	206.43	148.84
Upper molars	351.46	96.31	239.68	199.05
Lower molars	151.04	112.21	160.49	76.56

Invisalign showed a better fit at the gingival edge of the lingual aspect on upper premolars (Figure 5) ($F = 5.34$, $P = .0047$). No statistically significant differences were detected for the other points analyzed. No statistically significant differences were detected between the two aligner appliances regarding their fit on lower premolars (Figure 6).

For the upper molars, Invisalign exhibited a better fit ($P < .0001$, Figure 7) at the gingival edge of the buccal aspect. The CA-Clear Aligner showed a significantly better fit at the buccal maximum convexity and on the buccal cusp. Furthermore, the CA-Clear Aligner showed significantly better fit in the occlusal groove and on the palatal cusp of the aligner ($P < .0001$).

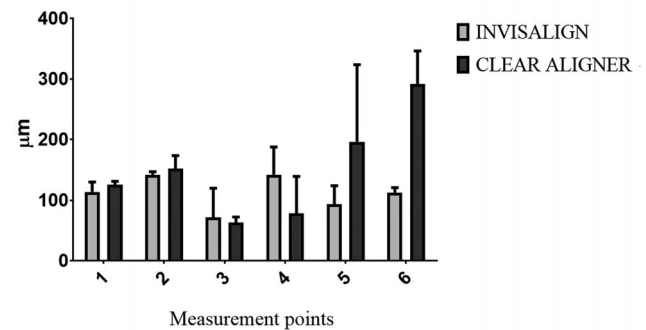
For the lower molars, Invisalign exhibited a better fit at the gingival edge of the aligner's buccal and buccal maximum convexity aspects ($P < .0001$). The CA-Clear Aligner showed a better fit on the palatal maximum convexity and on the gingival edge of the aligner's palatal aspect ($F = 20.07$, $P < .001$) (Figure 8).

DISCUSSION

Anchorage is important when planning orthodontic tooth movement. Since CAT success depends on anchorage management, it is important to note that no evidence regarding aligner fit on anchorage teeth is available even though the literature on efficacy and efficiency of CAT is increasing.² This *in vitro* study was a first attempt to measure and compare the fit of two different aligners. SEM photography and the measurements performed in this study provided useful clinical information related to the control of anchorage and orthodontic tooth movement (OTM). The fit of aligners for both of the systems investigated was excellent but Invisalign seemed to have an overall better fit considering data from the lower incisors and lower molars.

SEM demonstrated that Invisalign aligners provided a better fit in the gingival area of most of the analyzed teeth compared with the CA-Clear Aligner. However, the CA-Clear Aligner displayed a better fit than Invisalign in regions with more complex anatomy (ie, molar cusps).

TEETH-ALIGNER DISTANCE: UPPER INCISORS

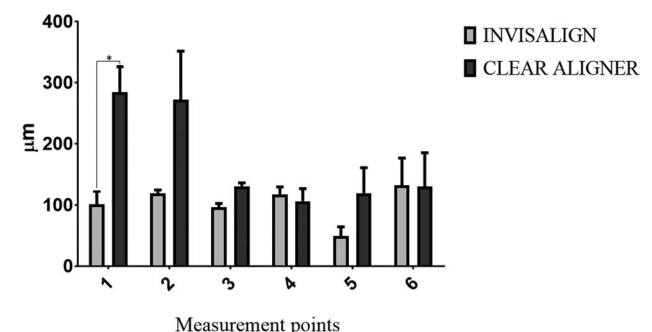
**Figure 3.** Aligner fit on upper incisors.

The plastic foil was thinned out by thermoforming at the gingival edge of the aligners, thus representing the area where they are less rigid.¹⁵ Therefore, the clinical result could be a loss of fit between the tooth and aligner in this area. According to the results of the current study, this loss of fit appeared to be higher for the CA-Clear Aligner. This result could have been due to higher stiffness of the CA-Clear Aligner material and to a different thermoforming procedure. The same characteristics could explain why the fit of the CA-Clear Aligner was more precise on complex occlusal surfaces.

The CA-Clear Aligner uses different thicknesses of aligner material during the different stages of treatment. In order to perform a comparable analysis for this study, the CA-Clear Aligner thickness of 0.5 mm¹⁶ was chosen for comparability to the thickness of Invisalign aligners²

Kohda et al.¹⁷ stated that the force released by thermoplastic appliances had a strong correlation with the hardness and elastic modulus of the materials. As shown by Lombardo et al.,¹⁸ aligners had intermediate mechanical properties between those of viscous and elastic materials. Furthermore, not every aligner was equal; those currently on the market differ in terms of their construction material, thickness, and clinical protocols.

TEETH-ALIGNER DISTANCE: LOWER INCISORS

**Figure 4.** Aligner fit on lower incisors.

TEETH-ALIGNER DISTANCE: UPPER PREMOLARS

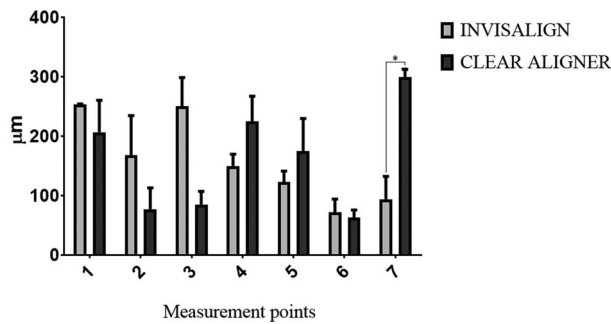


Figure 5. Aligner fit on upper premolars.

The width of the aligner’s edge was related to force delivery. Different aligner systems have various designs, for example: a scalloped gingival border (Invisalign) or a straight border with different widths (CA-Clear Aligner of 2–3 mm). Dasy et al.¹⁹ demonstrated that edgeless aligners generated significantly lower forces than did those with a wider edge. The increased force might be due to the enhanced stiffness caused by material shape. A higher retention force of the aligner and a decrease of flexibility of the material were associated with a larger gingival edge width.

In contrast, the measurements obtained in the current study demonstrated a better fit of the less stiff and, thus more flexible, aligner material. The difference may be explained by the fact that Dasy et al.¹⁹ analyzed aligners built with the same material (glycol-modified polyethylene terephthalate by Scheu Dental) while, in this study, the CA-Clear Aligner material was compared with Invisalign SmartTrack aligners, which are multilayer aromatic thermoplastic aligners. The exact composition of the material is patented. To achieve treatment success, it is important to know the material type and thickness so that the mechanical properties of the aligners can be understood.

TEETH-ALIGNER DISTANCE: LOWER PREMOLARS

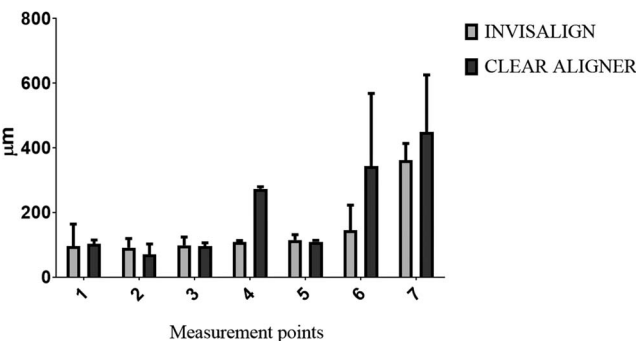


Figure 6. Aligner fit on lower premolars.

TEETH-ALIGNER DISTANCE: UPPER MOLARS

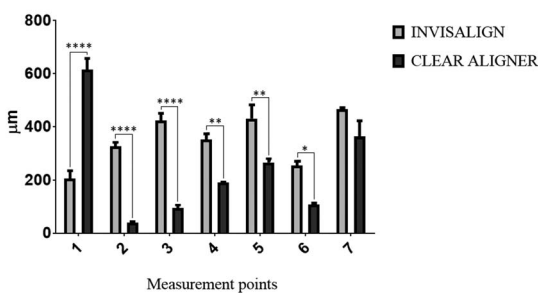


Figure 7. Aligner fit on upper molars.

Failure to adequately retain the appliance or incorporate as many teeth as possible into the anchor block are common causes of anchorage loss.²⁰ The use of excessive force or trying to move too many teeth at the same time may also result in unwanted movement of the anchor teeth. To avoid loss of anchorage, simultaneous movement of multiple teeth should be avoided. Planning CAT with virtual setup software facilitates choosing an appropriate number of anchor teeth and the proper sequence of tooth movement to minimize the risk of anchorage loss. However, clear aligner materials and geometries can influence the fit of the appliance on anchorage teeth. The present study demonstrated how two aligner systems may fit differently in different areas.

The main limitation of this study was the in vitro design. Future clinical studies are needed to examine whether the results can be confirmed. Another shortcoming was the small sample size that could not account for manufacturing tolerances, which produced a limited perspective that needs to be expanded in future studies. Additionally, several elements of aligner production are patented and therefore could not be considered to fully explain the differences observed.

Data related to the interaction between aligner and attachment characteristics are still lacking. Future studies focused on this interaction are needed. The true test of any aligner system is its ability to achieve

TEETH-ALIGNER DISTANCE: LOWER MOLARS

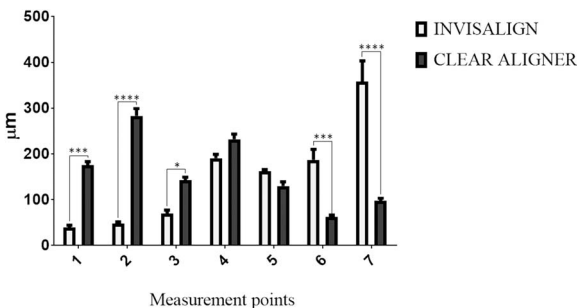


Figure 8. Aligner fit on lower molars.

the orthodontic goals of individualized treatment. Therefore, there is a need for clinical studies of single tooth movements guided by different designs of aligners and attachments. In this way, knowledge about orthodontics with aligners, its potential and limitations, can be learned for different aligner systems.

CONCLUSIONS

- Fit can be a critical determinant for the success of clear aligner therapy and establishment of effective anchorage.
- Invisalign and CA-Clear Aligner had comparable performance in terms of fit on teeth, but Invisalign showed overall better fit on lower incisors and lower molars.
- Invisalign displayed better fit at the gingival edges of the aligner, while CA-Clear Aligner had better fit on complex occlusal surfaces, such as on molars.

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